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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,562	09/16/2003	Nina Rautonen	17031	2985

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EXAMINER	
BLAND, LAYLA D	

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1623	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/663,562	RAUTONEN ET AL.	
	Examiner	Art Unit	
	LAYLA BLAND	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 January 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-13,16-19,24,26-28,30,32-35,38 and 40-56* is/are pending in the application.

4a) Of the above claim(s) *52-54* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5-13,16-19,24,26-28,30,32-35,38, 40-51, 55-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/26/2011*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 26, 2011 has been entered.

This Office Action is in response to Applicant's request for continued examination (RCE) filed January 26, 2011, and amendment and response to the Final Office Action (mailed July 26, 2010), filed January 26, 2011 wherein claims 1, 38, 45, and 47-49 are amended and claims 55-56 are newly submitted.

Claims 1, 5-13, 16-19, 24, 26-28, 30, 32-35, 38, and 40-56 are pending and are examined on the merits herein.

Claims 52-54 are withdrawn from consideration as being directed to a non-elected invention

Claims 1, 5-13, 16-19, 24, 26-28, 30, 32-35, 38, and 40-51, and 55-56 are examined on the merits herein.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 48-51 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stahl et al. (CA 2340103A1, February 2, 2000, of record) in view of Jie (Am J Clin Nutr 2000; 72:1503-9, PTO-1449 submitted November 17, 2003), Brokx et al. (WO 02/39832, May 23, 2002, of record), and Livesey et al. (European Journal of Clinical Nutrition (1993) 47, 419-430, of record).

Stahl teaches dietetic foods containing of a mixture of carbohydrates, which remain undigested in the gastrointestinal tract and reach the large intestine without being resorbed, wherein the carbohydrates have prebiotic action [see abstract]. The carbohydrate mixture contains at least compounds A and B, which remain undigested in the gastrointestinal tract and reach the large intestine unresorbed, wherein A is a monosaccharide or oligosaccharide and B is a polysaccharide [pages 3-4]. A prebiotically active carbohydrate reaches the large intestine undigested and encourages the growth and/or activity of bacterial species in the intestine, and consequently

promotes health [page 6, lines 1-6, and claim 12]. Preferably, the carbohydrates are bifidogenous and/or promote lactic acid bacteria [page 7, lines 28-30, and claim 3]. Carbohydrates A and B should be of a different size and structure [page 8, lines 27-31] so that a synergistic effect may occur [page 9, lines 9-14]. The combination of carbohydrates is more efficient than only one carbohydrate [page 7, lines 17-26]. The carbohydrate mixtures are effective for stabilization of natural microflora, prevention of pathogenous substances/organisms, and acceleration of wound healing [page 8, lines 13-20], and treatment of symptoms/diseases occurring in conjunction with disturbed intestinal flora [page 8, lines 22-25]. Normal intestinal flora might not be present in babies or in subjects who have taken antibiotics [page 2, lines 15-19]. Compositions include baby formula, human milk fortifier, pharmaceuticals, and dietetic supplements [page 13, lines 1-6, and claim 12].

Stahl's teaching of suitable carbohydrates is broad and Stahl does not expressly teach polydextrose and lactitol as the two carbohydrates.

Jie teaches that polydextrose is not digested or absorbed in the small intestine and increases the growth of favorable microflora [page 1503, first full paragraph in second column], such as Lactobacillus and Bifidobacterium species [see abstract].

Brokx teaches that lactitol is a prebiotic which improves intestinal microflora [see abstract], particularly Lactobacilli and Bifidobacteria [page 1, lines 26-28]. As such, it can be used to treat intestinal infections, colon cancer, diarrhea, or for enhancing immunity [claim 7].

Livesey teaches that the hydrogen breath test is used to detect the fermentation of carbohydrates that escape absorption in the small intestine, and works by measuring hydrogen produced by large-bowel-anaerobic microorganisms in the presence of fermentable carbohydrate [page 419, first paragraph]. The combination of polydextrose and lactitol doubled the breath hydrogen anticipated from their individual contributions, showing a positive interaction [see abstract].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to treat subjects such as babies or subjects who have taken antibiotics with a combination of polydextrose and lactitol. Stahl teaches that a combination of two carbohydrate prebiotics of different size can be used to treat these subjects. Polydextrose and lactitol are prebiotics and are of different size. Furthermore, the particular combination of polydextrose and lactitol produces a larger than expected effect in the hydrogen breath test, which measures fermentation of compounds in the bowel. Thus, the skilled artisan would choose the combination of polydextrose and lactitol for Stahl's method.

Claims 1, 5-13, 16-19, 24, 26, 27, 28, 30, 32-35, and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stahl in view of Jie, Brokx and Livesey as applied to claims 48-51 and 55 above, and further in view of Vella et al. (Mayo Clin Proc. 1998; 73:451-456) and Borden et al. (US 5,601,863, February 11, 1997, of record).

Stahl, Jie, Brokx, and Livesey suggest the combination of prebiotics polydextrose and lactitol for stabilization of intestinal microflora and for conditions occurring in conjunction with disturbed intestinal flora, but do not specifically teach short bowel or acidosis.

Vella teaches that acidosis is seen in patients with a shortened small intestine [page 451, first paragraph]. In patients with a short intestine, gut flora is abnormal, and abnormal colonic flora is central to the pathogenesis of acidosis [page 452, second full paragraph].

Borden teaches that polydextrose and hydrogenated polydextrose are both enzyme-resistant and functional equivalents as food additives [columns 1-2 and paragraph bridging columns 6-7].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to administer polydextrose and lactitol to a patient suffering from short intesting and/or acidosis. Stahl, Jie, Brokx, and Livesey suggest the combination of polydextrose and lactitol for conditions occurring in conjunction with disturbed intestinal flora, and Vella teaches that disturbed intestinal flora is a feature of patients having short intestine and acidosis. Thus, the prior art as a whole suggests administration of polydextrose and lactitol to a patient suffering from short intestine and acidosis. Polydextrose and hydrogenated polydextrose are functional equivalents, so the skilled artisan would use either.

Claims 38 and 40-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stahl in view of Jie, Brokx and Livesey as applied to claims 48-51 and 55 above, and further in view of Kaminogawa (Bioscience and Microflora, Vol. 21, No. 1, July 3, 2001, pp. 63-38, abstract only).

Stahl, Jie, Brokx, and Livesey suggest the combination of prebiotics polydextrose and lactitol for stabilization of intestinal microflora and for conditions occurring in conjunction with disturbed intestinal flora, but do not specifically teach the treatment of food allergy.

Kaminogawa teaches that prebiotics contribute to the stimulation of beneficial bacteria in the large intestine, inhibiting food allergy.

Stahl, Jie, Brokx, and Livesey suggest the combination of polydextrose and lactitol for conditions occurring in conjunction with disturbed intestinal flora, and Kaminogawa teaches that healthy intestinal flora is important for inhibiting food allergy. Thus, the prior art as a whole suggests administration of polydextrose and lactitol to a patient suffering from food allergy.

Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stahl in view of Jie, Brokx and Livesey as applied to claims 48-51 and 55 above, and further in view of Beyer (Medical nutrition therapy for lower gastrointestinal tract disorders, in Mahan LK, Escott-Stump S (eds): Krause's Food, Nutrition and Diet Therapy (ed 10), Philadelphia, PA, WB Saunders, 2000, pp 667-694, of record).

Stahl, Jie, Brokx, and Livesey suggest the combination of prebiotics polydextrose and lactitol for stabilization of intestinal microflora and for conditions occurring in conjunction with disturbed intestinal flora, but do not specifically teach the treatment of colon inflammation.

Bayer teaches that prebiotics or fermentable sugars can be used to treat diarrhea [page 710, first paragraph in the second column], lactose intolerance [page 720, second paragraph in the second column], inflammatory bowel disease [page 724, second paragraph], and pouchitis, which is an inflammatory condition related to bacterial overgrowth [page 735, first paragraph].

Stahl, Jie, Brokx, and Livesey suggest the combination of polydextrose and lactitol for conditions occurring in conjunction with disturbed intestinal flora, and Bayer teaches that inflammatory conditions of the bowel are related to bacterial overgrowth. Thus, the prior art as a whole suggests administration of polydextrose and lactitol to a patient suffering from inflammatory conditions of the bowel.

Claims 45-47 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stahl in view of Jie, Brokx and Livesey as applied to claims 48-51 and 55 above, and further in view of Borody (US 5,443,826, August 22, 1995, of record).

Stahl, Jie, Brokx, and Livesey suggest the combination of prebiotics polydextrose and lactitol for stabilization of intestinal microflora and for conditions occurring in conjunction with disturbed intestinal flora, but do not specifically teach the treatment of celiac disease and inflammatory bowel disease.

Borody teaches that disorders associated with abnormal microflora or an abnormal distribution of microflora in the gastrointestinal tract can be treated by restoring normal healthy flora [see abstract]. Celiac disease, inflammatory bowel disease, antibiotic associated colitis, irritable bowel syndrome, and small bowel bacterial overgrowth are examples of such disorders [column 3, lines 25-34].

Stahl, Jie, Brokx, and Livesey suggest the combination of polydextrose and lactitol for conditions occurring in conjunction with disturbed intestinal flora, and Borody teaches that celiac disease, inflammatory bowel disease, and antiobiotic colitis are related to bacterial overgrowth. Thus, the prior art as a whole suggests administration of polydextrose and lactitol to a patient suffering from celiac disease, inflammatory bowel disease, and antiobiotic colitis.

Response to Arguments

Applicant argues that Stahl and Gibson prefer inulin or fructo-oligosaccharides as prebiotics, that Gibson teaches that non-starch polysaccharides are not prebiotics, and that neither suggest polydextrose. Applicant's argument has been carefully considered but is not persuasive. Gibson's "non-starch polysaccharides" do not explicitly include polydextrose, and Gibson mentions only plant cell wall polysaccharides, hemicellulose, pectins, and gums as the non-starch polysaccharides. Gibson does not teach away from the use of polydextrose because polydextrose is not specifically mentioned and is not within the classes of polysaccharides mentioned by Gibson as non-starch polysaccharides. Furthermore, Jie clearly teaches that polydextrose has prebiotic

properties. Although Stahl does not teach polydextrose and lactitol, Stahl does teach the characteristics which the two sugars should have. Polydextrose and lactitol have those characteristics, and have been shown to interact positively with each other. The skilled artisan would use polydextrose and lactitol for this reason.

Applicant argues that Livesey does not indicate the prevention of disorders or prevention of lactic acid accumulation. As noted by Applicant, Livesey teaches that the fermentation rate is increased with the combination of polydextrose and lactitol. Polydextrose and lactitol promote the growth of beneficial intestinal flora, as set forth above, which is associated with a number of disorders, also set forth above. Livesey's teaching, in combination with the other teachings above, does suggest treatment of disorders.

Applicant argues that Jie teaches a drop in pH levels with polydextrose intake, which would aggravate a condition caused by lactic acid accumulation. This argument is not persuasive because the cited references above also teach that lactic acid acidosis is a result of abnormal microflora, which would be expected to be remedied by administration of polydextrose.

Applicant argues that lactitol is not a sugar at all and that polydextrose is not fermentable. The examiner provided references in the previous office action which recognize lactitol as a sugar alcohol, a disaccharide, and a carbohydrate. Jie teaches that polydextrose is fermented in the large intestine [page 1503, Introduction].

Applicant argues that Beyer teaches a large number of different ways to treat disorders in the gastrointestinal tract, and that sugar alcohols can worsen osmotic

diarrhea, and that dietary fiber is contraindicated in certain cases. However, Beyer also teaches that prebiotics are used to treat diarrhea [page 710, right column, first full paragraph] and for management of IBD [page 724, second full paragraph; page 726, right column, first paragraph and third paragraph]. The other cited references also teach the functions and benefits of prebiotics in various disorders.

Applicant argues the Borody teaches restoration of microflora using live bacteria from another donor, not by administering prebiotics. Indeed, Borody taken alone does not suggest the use of prebiotics. However, the use of prebiotics to restore healthy microflora is well known in the art, as shown by the other cited references. Thus, Borody taken with the other cited references does suggest administration of prebiotics.

For these reasons, the rejections are maintained.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAYLA BLAND whose telephone number is (571)272-9572. The examiner can normally be reached on Monday - Friday, 7:00 - 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anna Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Layla Bland/
Examiner, Art Unit 1623